EXHIBIT A

1.

COMMONWEALTH OF MASSACHUSETTS

BRISTOL, ss. **SUPERIOR COURT**

BRISTOL, SS SUPERIOR COURT
FILED
APR 17 2019
MARC J. SANTOS, ESQ.
CLERK/MAGISTRATE

CIVIL NO: 1973CV00360

DEANNA HOSKEY and WALTER HOSKEY, JR.,
Plaintiffs,

v.

DEPUY SYNTHES PRODUCTS, INC., and DEPUY SYNTHES SALES, INC.,
Defendants.

COMPLAINT

and

DEMAND FOR JURY TRIAL

THE PARTIES

1. The Plaintiffs, Deanna Hoskey and Walter Hoskey, Jr., are residents of Chandler, Arizona.

2. The Defendant, DePuy Synthes Products, Inc. is a Delaware corporation with its principal place of business located in Raynham, Massachusetts.

3. The Defendant, DePuy Synthes Sales, Inc. is a Massachusetts corporation with a principal place of business located in Raynham, Massachusetts.

JURISDICTION

4. Personal jurisdiction over the Defendants exists by virtue of their Massachusetts citizenship and their presence in the Commonwealth of Massachusetts, where they regularly conduct business and derive substantial revenue from goods used or consumed in the Commonwealth of Massachusetts.

VENUE

5. Plaintiffs file this Complaint in Bristol County as Defendants regularly conduct business in Bristol County and have a usual place of business in Bristol County.

GENERAL ALLEGATIONS

6. Defendants are exclusively responsible for the design, manufacture, and sale of the Synthes Radial Head Prosthesis System ("RHPS") which is the product at issue in this Complaint.

7. In or about June 2012, the RHPS was approved through the Food and Drug Administration's 510(k) approval process to be marketed in the United States for use in various elbow replacement surgeries.

8. As a 510(k) device, the Defendants must demonstrate that the device is "substantially equivalent" to another device already approved on the market and does not have to undergo rigorous clinical trials and tests to prove safety and efficacy.

9. In its application, Defendants stated that "[T]he proposed Synthes Radial Head Prosthesis has the same indications for use, the same fundamental technological characteristics, and similar materials as the predicate Biomet ExploRTM (K051385) and Ascension (K032686) Modular Radial Head Devices."

10. In a press release regarding the RHPS, Defendants' consultant, Harry Hoyen, stated: "This system is a comprehensive solution for the radial head replacement that permits the surgeon to choose whether a long or short stem is best for the proximal radius."

11. The purpose of the system is to restore joint function by replacing the radial had of the elbow. The radial head is at the top of the radius bone of the arm just below the elbow.

12. The system is designed to work as a replacement for those with degenerative or post-traumatic disabilities as well as those who have suffered radial head fractures that are beyond repair. The elbow implant was also indicated for revision, after radial head arthroplasty.

13. The elbow replacement surgery, or elbow transplant, involves implanting a head and a stem into the patient's elbow. The modularity of the system allows the surgeon to choose from 24 heads and 10 stems to achieve maximum fit and stability. During the surgery, the stem is fitted so that the bone grows around the device to keep it secure.

14. Not long after marketing the RHPS, multiple reports of elbow replacement surgery complications surfaced, and patients were reporting elbow implant loosening.

15. Between 2014 and 2016, the FDA received dozens of reports that the RHPS had loosened in patients and required revision surgery to repair, putting patients at risk of further infection and pain.

16. While elbow loosening alone is a serious issue, it can also lead to other complications, like osteolysis, an issue where the body attacks the bone cells and causes bones to become weaker.

17. On or about December 29, 2016, Defendants issued a recall of all 50,311 units of the RHPS due to the potential for the radial head to loosen at the bone interface.

18. In a notification to surgeons, Defendants explained, "Based on the currently available data, we believe the cause to be multifactorial (including possible product characteristics, operative and patient factors), but we have not been able to characterize these factors fully. Consequently, we have not been able at this time to issue further instructions to surgeons that might lead to a reduction in issue rate and have decided to remove the DePuy Synthes Radial Head Prosthesis Stem from the global market."

19. Defendants warned that potential problems with their RHPS could include poor joint mechanics, osteolysis, bone fracture, pain, soft tissue damage, and elbow implant loosening.

20. Healthcare practitioners who had implanted patients with the devices were told they should follow patients in the usual manner.

21. On or about February 2, 2017, the FDA issued a Class 2 Recall Notice of RHPS stating that the "Manufacturer's Reason For Recall: The radial stem may loosen postoperatively at the stem bone interface."

22. On or about June 17, 2017, a Medical Device Alert was issued in the United Kingdom by the Medicine and Healthcare Products Regulatory Agency recalling RHPS. The Alert warned not to implant these devices and to identify and advise all patients implanted with affected devices to contact their orthopedic surgeon if they develop symptoms such as pain, loss of function or instability, among others.

23. One of the biggest dangers of elbow implant loosening is that it is difficult to diagnose.

24. The RHPS recall states that elbow implant loosening can cause painful and severe side effects.

25. At all times relevant, Defendants were aware that metallic implants can loosen, fracture, corrode, migrate, disassociate at the head from the stem, or stem/bone interface and cause pain even after a fracture has healed.

26. Upon information and belief, Defendants failed to adequately test and/or issue proper warnings concerning the RHPS prior to marketing and after marketing the system in the United States.

27. On January 2, 2017, Plaintiff Deanna Hoskey suffered a Monteggia type fracture of the proximal ulna and radial head treated with open reduction and internal fixation and radial head implant arthroplasty utilizing Defendants' RHPS in accordance with the instructions and protocols of the Defendants.

28. Plaintiff continued to suffer pain and instability to regain functional use of her left arm and elbow.

29. On or about May 30, 2017, she was seen by Dr. Jon Zolton who documented elbow and wrist pain and opined that the ulna fracture appeared to be healing well.

30. On or about June 13, 2017, she was seen by for continued pain and limitations. Films revealed osteolysis at radial head and noted need for revision surgery in the future.

31. By July 12, 2017, x-rays revealed progressive osteolysis at the radial head implant.

32. On August 3, 2017, Dr. Neil Motzkin identified and removed the loose left radial head implant.

33. Upon information and belief, the RHPS was defective and malfunctioned as the stem loosened and head disassociated from the stem.

34. Upon information and belief, the RHPS was defectively designed and never underwent appropriate testing.

35. The Defendants provided surgeons and patients deficient and inadequate warnings and instructions.

36. The failure to properly instruct and warn surgeons and or their patients, rendered the product defective and unsafe for its intended usage and breach of warranty

37. The subject device was unsafe for its intended use because, at a minimum, the side loading radial head has the high probability of loosening post-operatively at the stem-bone interface. Further, the radial head defectively loosens from a variety of factors and alternative surfaces provide a superior coating process.

38. The RHPS was intended to restore joint function but failed to restore joint function in Plaintiff and caused secondary injury and delay in healing.

39. The subject device was dangerously defective when it was initially sold and marketed by the Defendants, and remained in substantially the same condition until implanted into the Plaintiff, injuring her.

40. As a result of the aforementioned conduct of the Defendants, Plaintiff suffered serious injury to her arm and elbow. Upon discharge to her home, Plaintiff required assistance with bathing and other daily activities. The Plaintiff's debilitating injuries have: (1) necessitated medical care and expenses; (2) necessitated multiple surgeries, and extensive rehabilitation; (3) temporarily rendered her incapable of working; (4) caused extraordinary physical pain and suffering and emotional distress and anguish; and (5) negatively affected the quality of her life by rendering her physically dependent on others and preventing her from enjoying normal day-to-day, social and recreational activities.

41. The injuries and damages suffered by the Plaintiff resulted from the failure of Defendants' device and were caused by and were the direct and proximate result of Defendants' breaches of warranty and/or its negligence or other wrongful conduct, in any or all of the following respects:

    a. in failing to properly design, manufacture, assemble, inspect and test the device;

    b. in selling, marketing and distributing the device in a dangerously defective condition;

    c. in selling and distributing the subject device that was not reasonably fit and suitable for its ordinary, intended and foreseeable purposes;

    d. in failing to properly inspect and test device;

    e. in failing to warn surgeons and patients of the device's risks and defective condition before, during and after sale and delivery of the device;

    f. in marketing and selling the subject device when it knew or should have known of its inherent design defects; and

    g. in failing to correct known design deficiencies in the subject device.

42. The injuries and damages sustained by the Plaintiff resulted from the failure of the subject device and were caused by and were the direct and proximate result of Defendants' breaches of warranty in that it sold, marketed, distributed and otherwise contributed to the placement of the subject device in a dangerously defective condition.

COUNT I

BREACH OF WARRANTY

43. The Plaintiff incorporates by reference all of the allegations contained in the foregoing paragraphs as if they were fully restated herein.

44. The breach of warranty and wrongful conduct of Defendants in designing, marketing and distributing the RHPS resulted in injuries of Plaintiff.

45. As a direct and proximate result of Defendants' breach of warranty, the Plaintiff is entitled to recover all allowable elements of damages under Massachusetts General Laws or any other

applicable law from the Defendants in an amount that is just and appropriate to fully compensate Plaintiff, plus interest and costs.

WHEREFORE, the Plaintiffs demand judgment against the Defendants in an amount that is just and appropriate to compensate her for the injuries and damages sustained, plus interest and costs.

COUNT II

PRODUCT DEFECT/PRODUCT LIABILITY

46. Plaintiffs incorporate by reference all of the allegations in the foregoing paragraphs as if they were fully stated herein.

47. The Defendants defectively designed and manufactured the RHPS such that it was unsafe for its intended use, and Defendants further over-promoted the benefit of the system given the defects and risk of injury inherent to the system.

48. Defendants failed to convey adequate warnings to the Plaintiff's physicians of the loosening of the implant system, and Defendants did not take reasonable measures prior to, during, or after the sale of this product so as to prevent harm to Plaintiff.

49. As a direct and/or proximate result of the aforementioned conduct of the Defendants, Plaintiff has suffered serious injuries, some or all of which may be permanent in nature.

50. As a direct and/or proximate result of the aforementioned conduct of the Defendants, Plaintiff has suffered physical pain and suffering, delayed healing, required revision surgery, psychological trauma, mental anguish, emotional distress, discomfort, inconvenience, embarrassment, and the loss of the ability to enjoy the pleasures of life, and will to continue to so suffer for an indefinite period of time into the future.

WHEREFORE, the Plaintiffs demand judgment against the Defendants in an amount that is just and appropriate to compensate her for the injuries and damages sustained, plus interest and costs.

COUNT IIII

NEGLIGENCE

51. Plaintiffs incorporate by reference all of the allegations contained in the foregoing paragraphs as if they were fully restated herein.

52. The Defendants, acting by and through their agents, servants, and employees, owed a duty to the Plaintiff to exercise reasonable skill and care in designing, manufacturing, marketing, and selling the subject device.

53. The Defendants, acting by and through its agents, servants, and employees, breached their duty of care and were negligent in the following respects:

    a. It negligently and carelessly designed the device;
    b. Failed to conduct adequate and thorough pre and post marketing testing of the device;
    c. Failed to disclose or timely disclose data which demonstrated risk of harm of device;
    d. It negligently and carelessly manufactured the device;
    e. It negligently failed to test and/or inspect the device before selling and marketing it;
    f. It negligently failed to rectify design and manufacturing deficiencies that resulted in failures in the device;
    g. It negligently and carelessly designed, manufactured, tested, sold and promoted a product which they knew or should have known to be unsafe for its intended use;
    h. It failed to adequately warn Plaintiff's surgeon and patient and medical community of the hazards and defects associated with the device, including:
        1. Stem loosening post insertion;
        2. Head falling off the stem during implantation due to design defect or radial prosthetic device instrument failure;
        3. No more taper, or back up screw in the absence of morse taper;
        4. Defective screw design;
        5. Failure of torque limiter;
        6. Malfunction;
        7. Implant screw defectively designed;
        8. Defective surface coating and or surface etching process;
        9. Screws provide inadequate screw purchase to keep head on;
        10. Inadequate safety mechanism to maintain screw position;
        11. Defective design of screw head
        12. Defective acid etching process;
        13. Unstable side loading;
        14. Trapezoid taper causing loosening;
        15. Screw has inadequate press fit;
        16. Screw threads can be damaged in trial screw use;
        17. Failure to validate and recalibrate torque limiter;
        18. Lack of integrity and modular connection;
        19. Violation of design and manufacturing standards;
        20. Improper or inadequate coatings;
        21. Disassociation between the radial head and stem; and/or
        22. Inadequate friction press to minimize micromotion to allow boney ingrowth.

54. Defendants' negligence includes the negligent design and manufacture of the product that was sold with the previously described defects, the failure to investigate information about the risks of the product, their decision to continue to sell the product in the face of increasing information that the product posed an unreasonable risk to patients and the failure to conduct adequate post-

sale surveillance of their products and failure to document and report adverse events related to their product in a timely manner.

55. If Plaintiff's surgeon had been provided with adequate warnings and instructions concerning the hazards of this implant, he would have heeded the warnings and instructions and avoided this product.

56. The negligence and wrongful conduct of the Defendants caused the failure of the device and resulted in the injuries and damages suffered by the Plaintiff.

57. As a result of the foregoing, the Plaintiff is entitled to recover all allowable elements of damages from the Defendants in an amount that is just and appropriate to compensate her fully for the serious, debilitating and permanent physical injuries, pain and suffering and mental anguish she has suffered, loss of income, plus interest and costs.

WHEREFORE, the Plaintiffs demand judgment against the Defendants in an amount that is just and appropriate to compensate her for the injuries and damages sustained, plus interest and costs.

COUNT IV

STRICT LIABILITY

58. Plaintiff incorporates by reference all of the allegations contained in the foregoing paragraphs as if they were fully restated herein.

59. At all times relevant, Defendants manufactured, designed, distributed, and /or sold RHPS.

60. At all times relevant, the dangerous propensities of RHPS were known to Defendants, or reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied or sold their devices, and not known to ordinary physicians who would be expected to use their product for their patients.

61. Defendants are strictly liable for designing a defective and unreasonably dangerous product and for failing to warn, which were both proximate and producing causes of the personal injuries and other damages suffered by the Plaintiff.

62. Defendants failed to correct known defects and or failed to timely recall replace or provide post-sale warnings of the known defects and of the unreasonably dangerous nature of the product.

63. As a result of the foregoing, Plaintiff is entitled to recover all allowable elements of damages from the Defendants, in an amount that is just and appropriate to compensate them fully for the serious, debilitating and permanent physical injuries, pain and suffering and mental anguish she has suffered, loss of income, plus interest and costs.

WHEREFORE, the Plaintiffs demand judgment against the Defendants in an amount that is just and appropriate to compensate her for the injuries and damages sustained, plus interest and costs.

COUNT V

FRAUDULENT AND NEGLIGENT MISREPRESENTATION

64. Plaintiffs hereby incorporate by reference all of the allegations contained in the foregoing paragraphs as if they were fully reinstated herein.

65. Upon information and belief, Defendants fraudulently misrepresented to Plaintiff, the FDA, and the general public the safety of RHPS and fraudulently concealed material facts, including adverse information regarding the safety of RHPS.

66. Upon information and belief, Defendants made representations and actively concealed adverse information at a time when Defendants knew RHPS had defects, dangers, and characteristics that were other than what the Defendants had represented to the FDA and the public, including Plaintiff.

67. Specifically, Defendants misrepresented to Plaintiff, Plaintiff's physicians, the general public and the FDA that RHPS was: safe when used as recommended; was fully and adequately tested; was as safe and effective as other similar devices.

68. Defendants knew that these representations were false and that the Plaintiff would rely on them.

69. Plaintiff and her physicians were unaware of the falsity of the statements being made and believed them to be true at the time they were made.

70. Plaintiff and her physicians justifiably relied on the false statements and misrepresentations of Defendants.

71. Defendants had a post-sale duty to warn Plaintiff and her physicians about the potential dangers and complications associated with RHPS.

72. As a direct and proximate result of the concealment and misrepresentations, Plaintiff suffered injuries.

WHERERFORE, the Plaintiffs demand judgment against the Defendants in an amount that is just and appropriate to compensate her for injuries and damages sustained, plus interest and costs.

COUNT VI

LOSS OF CONSORTIUM

73. Plaintiff Walter Hoskey, Jr. incorporates by reference all of the allegations contained in the foregoing paragraphs as if they were fully reinstated herein.

74. As a result of the Defendants' breaches of implied warranties and negligence and the injuries suffered by Deanna Hoskey as a result of her January 2, 2017 surgery, the Plaintiff, Walter Hoskey, Jr., was caused to endure the loss of his wife's society, companionship, cooperation, aid, affection and consortium of his wife, Deanna Hoskey.

WHEREFORE, the Plaintiff, Walter Hoskey, Jr., demands judgment against the Defendants, in an amount that is just and appropriate to compensate for his loss of consortium, plus interests and costs.

THE PLAINTIFF DEMANDS TRIAL BY JURY ON ALL COUNTS.

Respectfully submitted,

The Plaintiffs,
Deanna Hoskey and Walter Hoskey, Jr.

By their Attorneys,

KETTERER, BROWNE & ANDERSON

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